Nos. 15-2145(L), 15-2147

In The
UNITED STATES COURT OF APPEALS
For The Fourth Circuit

United States of America *ex rel.*
Brianna Michaels and Amy Whitesides,

Plaintiffs-Appellants,

v.

Agape Senior Community, Inc.; *et al.*

Defendants-Appellees,

v.

United States of America,

Intervenor-Appellee

BRIEF OF DEFENDANTS-APPELLEES AGAPE SENIOR COMMUNITY INC., *ET AL.* REGARDING STATISTICAL SAMPLING

Deborah B. Barbier
Deborah B. Barbier Attorney at Law
1531 Laurel Street
Columbia, SC 29201
803.445.1032
dbb@deborahbarbier.com

William W. Wilkins
Kirsten E. Small
Mark C. Moore
William C. Lewis
Nexsen Pruet, LLC
Post Office Drawer 10648
Greenville, SC 29603
(864) 370-2211
BWilkins@nexsenpruet.com
KSmall@nexsenpruet.com

Counsel for Defendants-Appellees
Agape Senior Community Inc., et al.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

RULES

REGULATIONS

STATEMENT OF THE CASE

Defendants-Appellees (collectively, "Agape") are affiliated entities that operate healthcare facilities throughout the state of South Carolina. J.A. 469. During the time relevant to this litigation, Agape offered a broad range of services including assisted living, skilled nursing, rehabilitation services, and home care for seniors.

This *qui tam* action was filed by two former Agape employees, Brianna Michaels and Amy Whitesides (collectively, "Relators" or "the *Michaels* Relators"), who worked at an Agape facility in Rock Hill, South Carolina. J.A. 49-50. Relators assert numerous causes of action, but their central allegation is that Agape fraudulently billed Medicare for hospice services that were actually provided but which were not medically necessary. Relators contend that Agape stood to gain financially by placing ineligible patients in hospice care and also artificially inflating their need for higher levels of care. *But see* J.A. 105-106 (explaining that Relators' theory is "fatally flawed" because Medicare imposes caps on payments for hospice care). Although Relators allege that Agape engaged in a variety of improper actions, their complaint ultimately rests on the allegation that Agape provided hospice services to patients who were not eligible for hospice, *i.e.*, they did not have terminal illnesses.[1]

[1] Relators' apparent belief that Agape's hospice patients were not "sick enough" to be in hospice reflects an outdated view of hospice as a last refuge for patients in the final stages of a rapidly terminal illness, such as cancer. *See* Amanda Jacobowski, *Calculating Death: Implications of the Six-Month Prognosis Certification Requirement for the Medicare Hospice Benefit*, 19 Elder L.J. 187, 194-95 (2011) (hereinafter Jacobowski, *Calculating Death*) (describing "The Changing Face of the Hospice Patient"). Since the first hospice programs appeared in the

A. The Medicare Hospice Benefit

The Medicare Hospice Benefit was established to provide hospice care to terminally ill beneficiaries. Before a Medicare beneficiary may be placed on hospice care, the patient's attending physician and either the hospice medical director or a hospice physician must certify that, in their clinical judgment, the patient is terminally ill, i.e., the patient "has a medical prognosis that the individual's life expectancy is 6 months or less." 42 U.S.C. § 1395f(a)(7)(A)(i) (eligibility requirements); 42 U.S.C. § 1395x(dd)(3)(A) (definition of "terminally ill"). *See generally* Ctr. for Medicare & Medicaid Servs., Medicare Benefit Policy Manual Ch. 9 ("Manual"), § 10. Certification for hospice eligibility is thus "based upon a physician's subjective clinical analysis" involving "a complex assessment influenced by the unique facts and circumstances associated with

---

1970s, however, the percentage of hospice patients with a diagnosis of cancer has declined, while the percentage of hospice patients with other conditions—such as heart disease, stroke, Alzheimer's, and kidney failure—have increased. *See id.*

This evolution of the hospice patient population has been accompanied by longer stays in hospice care. Hospice patients with terminal cancer "have a much quicker and more predictable course before death" than hospice patients with other diagnoses. Michael D. Cantor, *Making Tough Choices*, 2004 U. Ill. L. Rev. 183, 187 (2004). In contrast, for hospice patients with non-cancer diagnoses, "[t]he timing of death is hard to predict: in one large study of patients with a prognosis of six months or less, physicians did no better than fifty-fifty in prognosticating whether a patient would survive to discharge." *Id.* Of the 1.45 million patients admitted to hospice in 2008, only about 963,000 (66 percent) died in hospice care. *See* Jacobowski, *Calculating Death*, at 190-91. Of the remaining 488,000 patients, 276,000 were still alive and in hospice care in 2009, and 212,000 "were 'live discharges' who left [hospice] during 2008 to pursue curative treatment or as a result of improved prognosis." *Id.*

that individual." J.A. 283. The determination that a patient is terminally ill may be based on a single diagnosis, a combination of illnesses, or even without a specific diagnosis. J.A. 284; Manual § 10; *see also* Hospice Care Amendments Final Rule, 70 Fed. Reg. 70532, 70534 (Nov. 22, 2005) ("[T]he certification of an individual who elects hospice … shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness."). After being admitted to hospice care, the patient's eligibility for hospice must be recertified every 60 or 90 days. *See* 42 U.S.C. § 1395f(a)(7)(A)(ii). However, there is no limit to the amount of time a patient can spend in hospice care. *See* Manual § 10 ("Predicting life expectancy is not always exact. The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.").

There are four levels of hospice care:

- Routine care is provided in the patient's home or in a long term care facility, and may entail services from a hospice nurse, chaplain, social worker, or home-health aid. *See* Manual § 40; J.A. 285.
- General Inpatient ("GIP") care is hospice care that is provided in an inpatient setting "when the patient's medical condition warrants a short-term inpatient stay for pain control or acute or chronic symptom management that cannot feasibly be provided in other settings." Manual § 40.1.5.
- Respite care is short-term inpatient care, provided for the purpose of relieving family members or others caring for the patient at home. *See* Manual § 40.2.2.
- Continuous home care is home-based, 24-hour care by a hospice nurse during "a period of crisis" when continuous nursing care is needed "to achieve palliation or management of acute medical symptoms." Manual § 40.2.1.

See also J.A. 285-286. Determining whether a patient is eligible for hospice services, and the appropriate level of care, requires the certifying physician to consider "the patient's diagnosis, conditions, medical history, the nature or amount of care required, and many other factors." J.A. 287.

B. Relators' Allegations

As noted above, Relators allege that Agape submitted claims to Medicare for hospice services (primarily, routine hospice and GIP care) that were false because the patient either was not eligible for hospice services, or was not eligible for the level of services provided. Under this general umbrella, Relators alleged that several specific fraudulent practices sometimes occurred:[2]

- Patient certifications were not signed, or were not timely signed, by physicians;
- Certifications did not explicitly state that a patient's medical diagnosis qualified the patient for hospice care;
- Physicians signed hospice certifications without having seen the patient;
- Hospice certifications did not accurately reflect the treating physician's assessment;
- Nurses were instructed to put negative information on patients' charts or to admit patients to hospice or GIP services that were unnecessary.

J.A. 266.

[2] It is important to note that the Relators do not allege that each and every claim submitted by Agape was false.

C. *Rush* Complaint and Government Investigation of Agape

Relators filed their complaint under seal on December 7, 2012. J.A. 14; *see* 31 U.S.C. § 3730(b)(2) (requiring *qui tam* complaints to be filed under seal). The Government declined intervention on March 5, 2013, J.A. 72, and the district court unsealed the complaint two days later, J.A. 74. The following week, a second *qui tam* action, captioned *United States ex rel. Rush v. Agape*, D.S.C. No. 3:13-cv-00666, was filed under seal. Similar to the complaint in this case, the *Rush* complaint alleged that Agape had certified patients for hospice or GIP services for which they were not eligible. J.A. 229-230. At the Government's request, the district court partially lifted the seal in the *Rush* case, allowing the Government to share the complaint with the *Michaels* Relators. J.A. 223.

The Government eventually declined to intervene in the *Rush* case, but before doing so it requested multiple extensions of the seal period. The Government used this time to conduct an extensive—and for Agape, time-consuming and expensive—investigation under the auspices of the FCA. J.A. 662-663. During that time, Agape produced roughly 400,000 pages of documents in response to civil investigative demands (CIDs) authorized by the FCA. J.A. 654. Agape's request that its employees be contacted through counsel was ignored. J.A. 663. In one incident, FBI and IRS agents showed up, uninvited and unannounced, at the door Agape's Chief Financial Officer at 7:00 am. *Id.* By its own count, the Government interviewed some 55

individuals. J.A. 706.[3] Much of the information gathered by the Government during its investigation of the *Rush* complaint was provided to counsel for the *Michaels* Relators. J.A. 442.

By order dated August 18, 2014, the district court ruled that the *Michaels* Relators were the first to file as to all claims, and accordingly dismissed the *Rush* complaint. J.A. 222-38.

D. The Statistical Sampling Issue

Although Relators worked at only a single Agape facility in Upstate South Carolina, they asserted FCA violations against Agape facilities throughout the state. J.A. 123. Furthermore, despite their limited tenure at Agape, Relators asserted multiple forms of misconduct, J.A. 266, occurring over a period of nearly ten years. J.A. 584. Consequently, Relators' allegations encompassed a massive number of patients and claims. By the district court's estimate, J.A. 470, Relators' claims encompass between 10,166 and 19,820 individual patients, for whose care Agape submitted between 53,280 and 61,643 claims to Medicare. Importantly, however, Relators have *never* asserted that all of the claims submitted by Agape during the relevant period were false.

[3] One of those individuals was Kevin McHugh, a former Agape employee who, in violation of his separation agreement, had retained documents that should have been returned to Agape, many of which were subject to the attorney-client privilege. J.A. 664-665. During the litigation, Agape learned that the Government had obtained these improperly retained documents by requiring McHugh to produce them pursuant to a CID. *Id.* When this issue was brought to the district court's attention, the court ordered McHugh and the Government to return the documents. J.A. 29 (text order of July 28, 2014, ECF No. 139).

J.A. 339 ("It's not our allegation that every single [hospice] admission by Agape is a false claim."). However, as noted in Agape's district court filings, the Relators made little effort to conduct the review necessary to determine the universe of claims they actually contended were false.[4]

In August 2014, while discovery was still ongoing and before they had completed any meaningful review of claims data or medical records, Relators moved to stay the expert disclosure deadline set by the consent scheduling order. (ECF No. 146) During the hearing on that motion, Relators advised the district court that they intended to use statistical sampling and extrapolation of data to establish Agape's liability under the FCA. J.A. 204. Agape opposed this novel use of statistical sampling, pointing out to the court that determining an individual's eligibility for hospice care requires an exercise of subjective clinical judgment that takes into account myriad facts and circumstances unique to each patient, making statistical sampling entirely inappropriate to prove either liability or damages. J.A. 215.

---

[4] While the motion to allow statistical evidence was pending, Relators moved to compel Agape to give them unlimited, direct access to patients' electronic medical records through Agape's internal computer network. (ECF No. 179) Agape opposed the motion, pointing out that it could not give Relators access to hospice-patient records for the relevant period without giving them access to the *entire database*, including the medical records of Agape patients who were never on hospice. (ECF No. 182, at 3) The district court rejected Relators' proposed solution to this problem (that Agape produce a list of "irrelevant" patients so Relators would know which records not to look at) and denied the motion to compel remote access. J.A. 291. *Accord In re Ford Motor Co.*, 345 F.3d 1315, 1316 (11th Cir. 2003) (summarily reversing discovery order that granted plaintiff "unlimited, direct access to Ford's databases").

The district court expressed substantial skepticism about the propriety of using statistical evidence, but deferred a ruling until the parties could brief the issue. J.A. 220. The following week, Relators filed a "Motion to Permit the Use of Statistical Sampling," J.A. 239, accompanied by a six-page memorandum in support.[5] The same day, and despite the fact that it had declined to intervene and thus was not a party of record, the Government filed a "Statement of Interest" (ECF No. 167) that contained *nineteen full pages* of argument supporting Relators' motion.[6] After Agape filed its opposition, Relators and the Government both filed replies in support of Relators' motion. The Government also presented argument during the hearing on Relators' motion, taking care to inform the district court that the use of statistical sampling to prove

[5] Relators failed to explain below or in their brief how the statistical sampling would apply to the differing allegations of wrongdoing. For example, Relators failed to distinguish how statistical sampling would apply in regards to false certification based on misrepresentation as opposed to knowing lack of medical necessity.

[6] As the district court noted in its Order certifying issues for appeal, even though it declined intervention, the Government was an "active participant" throughout the litigation, "attending court hearings, taking positions on various procedural matters, filing briefs on substantive issues to be decided by this Court, attending depositions, and requesting extensions of time." J.A. 479. As the district court also noted, the Government objected to the settlement negotiated by the parties, asserting that the settlement amount was too low in comparison to its valuation of the case. The Government refused to explain its methodology in any detail, saying only that it had "arrived at its potential recovery figure by using an 'error rate' in the '20-60% range' derived from an expert review of … 'cherry picked' claims." J.A. 473. It was thus clear to the district court that the Government's objection to the settlement was based on "some form of statistical sampling that this Court has rejected for use at the trial of this case." *Id.*

liability in FCA cases "is an issue that's very important to the Department [of Justice]." J.A. 322.

The district court denied Relators' motion in a brief order stating that, after careful study, the court had concluded that "based on the facts of this case, statistical sampling would be improper." J.A. 422. The district court explained its reasoning in more detail in its order certifying questions for interlocutory review. J.A. 480-485. The court began by noting that when evidence has dissipated, "statistical sampling is sometimes the only way for a *qui tam* plaintiff-relator to prove damages." J.A. 481. In this case, by contrast, "nothing has been destroyed or dissipated. The patients' medical charts are all intact and available for review by either party." *Id.* After surveying the existing case law regarding the use of statistical sampling in FCA cases, the district court ultimately concluded that statistical sampling should not be used to prove liability:

> Distilled to its essence, each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary. Answering that question for each of the patients involved in this action is [a] highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. As the Court has acknowledged, some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages can be proved. This civil action, however, is not such a case.

J.A. 484-85.

E. Bellwether Trials

The district court's ruling on statistical sampling ruling left the parties and the court wrestling with the question of how to try the case, given that each patient's medical condition and eligibility for hospice services would have to be individually litigated. The court suggested that the parties conduct a "bellwether" trial[7] as to 100 patients of Relators' choosing. J.A. 321-22. Agape objected to this method, but the district court ordered the trial to proceed under a plaintiff-picked bellwether scheme.[8] J.A. 195. The district court reasoned that a bellwether trial "is particularly appropriate in this case because unlike large class action, which most often involve a significant degree of overlap regarding common issues, each and every claim at issue in this case is fact-dependent and wholly unrelated to each and every of other claim."

Relators originally selected 95 Agape patients for the bellwether trial. Thereafter, Relators voluntarily reduced this number to 38 patients.[9] Before the bellwether trials began, however, Relators and Agape entered into a negotiated

[7] In a bellwether trial, a sample of claims is tried to a jury, the premise being that the information obtained from a jury verdict on some of the claims will facilitate settlement of the remainder. *See Briggs v. Merck Sharp & Dohme*, 796 F.3d 1038, 1051 (9th Cir. 2015).

[8] Ordinarily, bellwether trials involve a mixture of claims picked by each side or drawn randomly. In this case, however, Relators were allowed to "cherry pick" the entire sample.

[9] The Relators later agreed to dismiss with prejudice all claims associated with the 57 patients removed from the original group of 95.

settlement with the aid of United States Magistrate Judge Mary Gordon Baker as mediator.[10]

F. The Settlement Veto Issue

Shortly after being notified of the settlement, the Government informed Relators and Agape that it intended to object to the settlement. The Government's position was that the value of the case was substantially higher than the agreed-upon settlement amount, and consequently the settlement amount was too little to justify releasing from Agape from potential liability on all claims encompassed by Relators' second amended complaint. As the district court observed, however, the Government's valuation did not account for the fact that the court had rejected the use of statistical evidence:

> The Government arrived at its potential recovery figure by using an 'error rate' in the '20-60% range' derived from an expert review of what the Government refers to as 'cherry picked' claims. While the Government's methodology for evaluating this case is not altogether clear to this Court, suffice it to say that the Government has used some form of statistical sampling extrapolated to the universe of potential claims in its damages calculation.

J.A. 472-473. Relying on 31 U.S.C. § 3730(b)(1), the Government contended that the district court had no authority to overrule its objection to the settlement, J.A. 473, notwithstanding the court's view that "a compelling case could be made" that the Government's objection to the settlement was unreasonable, J.A. 477.

[10] The events surrounding mediation and settlement are discussed in more detail in Agape's brief on the settlement veto issue.

Concluding that the circumstances "crie[d] out for interlocutory appeal," J.A. 485, the district court *sua sponte* certified two questions for interlocutory review pursuant to 28 U.S.C. § 1292(b): "(1) the Government's right to reject a settlement in a *qui tam* action to which it has not intervened" (the "settlement veto issue"; "and (2) the Plaintiff-Relators' use of statistical sampling to prove liability and damages" (the "statistical sampling issue"). J.A. 486. Agape petitioned for review of the settlement veto issue, and Relators petitioned for review of both issues. This Court granted both petitions, J.A. 577.

SUMMARY OF ARGUMENT

Relators have known from the very beginning of this litigation that they bear the burden of proof, and that to carry that burden they will have to prove that numerous physicians, many of whom are entirely unaffiliated with Agape, falsely certified—in other words, *lied about*—their patients' eligibility for hospice care.[11] There is no informational barrier that would prohibit Relators from attempting to prove every one of their claims: the medical records for the entire universe of patients encompassed by the allegations of the Second Amended Complaint exist in either paper or electronic form, and those records have been available to Relators since April 2014.

Relators do not claim that every hospice claim submitted during the relevant period violated the FCA. Nevertheless, Relators appear never to have conducted or completed an analysis of the information produced or made available by Agape, or given to them by the Government, that might enable the parties and the court to distinguish the allegedly false claims from the concededly valid ones.[12] Instead, Relators asked the district court to let them sidestep their burden of proof (and along with it, Agape's due process rights) by using statistical evidence to establish liability. Relators' efforts in this regard

[11] As discovery proceeded, Agape contacted a number of physicians whose hospice-eligibility certifications were covered by the allegations in Relators' complaint. Their response was universally the same: "They are saying, 'What is this about and who is saying I falsified what?' They don't work for Agape…. They are not happy and they want to come to court and defend the decisions they made as to these patients." J.A. 318.

[12] Relators did not even ask for the medical records related to the patients identified in their complaint until December 9, 2014.

have been aggressively supported by the Government, which reaps huge profits from *qui tam* actions. For example, in 2012 (the year Relators filed this action) the Government's take from FCA cases was more than $3 billion—the great majority of which was recovered in healthcare cases. *See* "Fraud Statistics," *available at* www.justice.gov/civil/documents-and-forms-0 (last visited Mar. 17, 2016).

The degree of the Government's involvement in this case is worthy of note. Although the Government formally declined intervention in early 2013, it has always participated in the litigation at all times, so actively that during one hearing, the district court pointedly asked counsel for the Government, "Ms. Warren, the Government is either in this case or out of this case. Which is it?" J.A. 413. The answer appears to be: The Government is in when it wants to be, and out when it doesn't.

The Government's extensive involvement in this litigation has included the following:

- Taking legal and factual positions in this litigation by filing numerous written pleadings and presenting argument at hearings;
- Using civil investigative demands and other investigative tactics to obtain documents (which were then shared with Relators' counsel), conduct interviews, and depose witness, often without notice to Agape;

- Providing its expert's work product to Relators (but not to Agape), effectively giving Relators 32 pre-packaged, cherry-picked claims for the bellwether trial (*see* ECF No. 222);[13]
- Attending the depositions conducted by the parties;
- Asking the district court to modify the scheduling order; and
- During the first mediation, making the primary presentation to the mediator.

At the same time, the Government has used its non-intervention to shield itself from having to comply with the Federal Rules of Civil Procedure and the Local Rules of the District of South Carolina, to Agape's disadvantage.

[13] Relators then identified the Government's expert as their own expert in an untimely "Amended Disclosure of Expert Witnesses," forcing Agape to file a motion *in limine* to exclude the witness. (ECF No. 227)

ARGUMENT

Relators asked the district court, and now ask this Court, to barge in where other courts fear to tread by allowing them to use statistical sampling and extrapolation to prove the critical elements of False Claims Act liability—the *knowing* submission of *false* claims—in a case that turns on physicians' clinical judgments regarding the condition, prognosis, and medical needs of their patients. After carefully considering the written and oral arguments of the parties, and thoroughly reviewing the extant case law, the district court concluded that while statistical sampling may be an appropriate means of proof in some FCA cases, it is not appropriate for *this* case. This conclusion is well within the district court's substantial discretion, and this Court should affirm.

I. STANDARD OF REVIEW

The admission or exclusion of evidence is reviewed for abuse of discretion. *See Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 161 (4th Cir. 2012). To establish that the district court's rejection of statistical evidence is an abuse of discretion, Relators must show that the court "act[ed] in an arbitrary manner, … fail[ed] to consider judicially-recognized factors limiting its discretion, or … relie[d] on erroneous factual or legal premises." *United States v. Henry*, 673 F.3d 285, 291 (4th Cir. 2012).

II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN REJECTING THE USE OF STATISTICAL SAMPLING TO PROVE LIABILITY.

A. Key Elements of FCA Liability: Falseness and Knowledge

The False Claims Act, 31 U.S.C. § 3729-3733 ("FCA"), imposes civil liability on an individual who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729 (a). Four elements must be proven to establish a defendant's liability under the FCA: "(1) a false statement or fraudulent course of conduct; (2) made with the requisite scienter; (3) that is material; and (4) that results in a claim to the Government." *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (citing *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003)).

1. Falseness

To prevail, the Relators must prove "the actual submission of a false claim." *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440 (3d Cir. 2004). In fact, "the submission of a false claim is the *sine qua non* of a False Claims Act violation." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2002); *see United States v. Kernan Hosp.*, 880 F. Supp. 2d 676, 686 (D. Md. 2012) (same). The Relators cannot carry their burden of proving a false claim without evidence that a particular "reimbursement claim [was] false or

fraudulent." *Visiting Nurse Ass'n of Brooklyn v. Thompson*, 378 F. Supp. 2d 75, 99 (E.D.N.Y. 2004).

A claim may be "false" for purposes of FCA liability in either a factual or a legal sense. *See United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 382 (1st Cir. 2011). A claim is "factually false" when it rests on a misrepresentation of the goods or services provided. *See id.* In the Medicare context, factual falsity requires proof of "an inaccurate description of goods or services provided, or a request for reimbursement for goods or services never provided." *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011). Upcoding—billing Medicare for a more expensive procedure than the one actually performed—is one type of factual falsity. *See United States v. Semrau*, 693 F.3d 510, 514 (6th Cir. 2012).

In this case, Relators do not allege that any claim submitted by Agape was factually false. Relators have never suggested, for example, that Agape billed for hospice services it did not provide, or that Agape provided hospice care at one level but billed Medicare for a higher level of hospice care. Rather, Relators assert that some of Agape's hospice patients did not meet the medical criteria for the type of care they received, and consequently, claims submitted for that care were *legally* false. *See Wall*, 778 F. Supp. 2d at 718 (ruling that a claim is legally false when "it involves a knowingly false certification of compliance with a statute or regulation, when that certification is a prerequisite to payment of the asserted claim"). A false certification may be either express or implied. *See Triple Canopy*, 775 F.3d at 635.

2. *Knowledge*

Relators must also prove scienter, *i.e.*, the *knowing* submission of a false claim for payment. It is not enough for Relators to prove that patients were falsely certified as eligible for hospice care; they must also establish that the Agape entity submitting the claim for that care knew the certification was false. This requires more than simply "'piecing together scraps of 'innocent' knowledge held by various corporate officials.'" *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1275 (D.C. Cir. 2010) (quoting *Harrison*, 352 F.3d at 918 n.9). Rather, Relators must prove "that a particular employee or officer [of the relevant Agape entity] acted knowingly." *United States v. Fadul*, 2013 WL 781614, at *9 (D. Md. Feb. 28, 2013).

B. Relators' FCA claims cannot be proved by statistical sampling.

Statistical evidence is poorly adapted to proving the falsity and knowledge elements of FCA liability generally, and it is particularly ill-suited for use in a case that, like this one, involves an exercise of clinical judgment—whether a patient is terminal—that is highly individualized, context-specific, and uncertain. While "clinical medical judgments are not automatically excluded from liability" under the FCA, courts agree that "FCA liability must be based on an objectively verifiable fact." *United States ex rel. Landis v. Hospice Care of Kansas, LLC*, 2010 WL 5067614, at *4 (D. Kan. Dec. 7, 2010); *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. Appx. 980, 983 (10th Cir. 2005) (same; dismissing FCA allegations where "clinical diagnoses and

characterizations of medical care" were ambiguous). Because "a physician must use … clinical judgment to determine hospice eligibility, … an FCA complaint about the exercise of that judgment must be predicated on the presence of an *objectively verifiable fact* at odds with the exercise of that judgment." *Wall*, 778 F. Supp. 2d at 718. As one district court recently ruled in a case very similar to this one, a mere "difference of opinion among physicians … is insufficient to support a finding that a claim is false." *United States v. AseraCare*, ___ F. Supp. 3d ___, 2015 WL 8486874, at *11 (N.D. Ala. Nov. 3, 2015).

The factors relevant to a patient's eligibility for hospice care are multifaceted, complex, and highly individualized. Indeed, the applicable regulations explicitly forbid the use of "check boxes or standard language used for all patient" in hospice-eligibility certifications. 42 C.F.R. § 418.22(b)(3)(iv). Relevant considerations may include (but by no means are limited to) the following:

- Gender;
- Age;
- Disease(s);
- Condition(s) (e.g., physical disability, dehydration, delirium, acute anxiety, weight loss, fluid retention, incontinence, respiratory symptoms, etc.);
- Other physician directives;
- Level of care needed (*e.g.*, general inpatient care ("GIP") services, routine care, etc.);
- Number of medications and dosage amounts;
- Adverse events (*e.g.*, falls, infections, wounds, overdoses, etc.);

- Assistance needed with activities of daily living; and
- Quality of life issues (*e.g.*, family support).

J.A. 284. In every case, the certifying physician must make a *subjective* judgment regarding the patient's prognosis and the level of care required. *See id.*

"The statutory phrase 'known to be false' does not mean 'scientifically untrue,' it means 'a lie.'" *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 628 (S.D. Ohio 2000). For this reason, "scientific judgments … about which reasonable minds may differ *cannot* be false." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1360 (S.D. Fla. 2015) (internal quotation marks omitted; emphasis added). Therefore, Relators cannot prevail merely by showing that the treating physicians *erred* in finding their patients eligible for hospice care; Relators must prove that the treating physicians "did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care." *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012).

Of necessity, therefore, Relators' allegations call into question the clinical judgment, not to mention the honesty and integrity, of numerous physicians, many of whom have no affiliation with Agape other than their decision to refer a patient to an Agape facility. Although Relators do not seek to impose FCA liability on the certifying physicians, those individuals nevertheless should not have their professional skills and ethics impugned based on extrapolation from a sampling of claims, regardless of how "statistically valid" such a sample may be.

In the Second Amended Complaint, the Relators allege that Agape engaged in the following conduct:

- Patient certifications were not signed or "timely" signed by physicians (¶ 63(a)(1)(A)-(C));
- Hospice patient certifications did not state that a patient's medical diagnosis qualified them for hospice status (¶ 63(a)(1)(D));
- Physicians signed hospice patient certifications for hospice care without having seen patients (¶ 63(a)(1)(E));
- Hospice patient certifications did not accurately reflect the treating physician's assessment (¶ 63(a)(2)(A)); and
- Nurses were instructed to chart negative information in patient files or admit patients for hospice or GIP services even when unnecessary (¶ 63(a)(2)(B)).

J.A. 266. However, none of these factors can enlighten a trier of fact as to the critical question of whether a given patient was eligible for hospice care (*i.e.*, whether that patient was terminal). An absent or untimely physician signature, for example, reveals nothing at all about a patient's medical condition. Moreover, "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). There could be "completely innocuous alternative explanations" for why patients were diagnosed or treated a certain way. *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 66 (D.D.C. 2007). Aggregate data does "nothing to identify [the] cause" for physician diagnoses, "let alone establish liability." *Id.* at 65. Thus, it is "imperative for [R]elator[s] to produce real evidence to support their

contention[s.]" *Id.* at 66; *see also, e.g., United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (affirming lower court summary judgment ruling because relator's evidence "failed to detail any particular false claim or even to provide sufficiently detailed circumstantial evidence of such a claim"). By this Motion, the Relators seek to completely avoid this burden and have the Court presume liability exists. Such a result is patently inappropriate.

C. Courts have consistently rejected attempts to use statistical sampling to prove liability in fraud cases.

Relators seek to rely on aggregate data—as opposed to direct proof— to establish that Agape patients were falsely certified to be eligible for hospice care. Although Relators and the Government repeatedly insist that courts routinely accept statistical evidence to prove liability, a review of relevant decisions makes clear that this is not so. To the contrary, courts have consistently rebuffed attempts to use extrapolated data to prove liability in fraud cases.

For example, in *United States v. Skodnek*, 933 F. Supp. 1108 (D. Mass. 1996), the Government sought to use extrapolated data to establish the amount of loss from the defendant psychiatrist's fraudulent practice of "upcoding," by providing a 30-minute therapy session but billing for a 60- or 90-minute session. *See id.* at 1114. The government "figur[ed] the rate of upcoding … from a known sample of the defendant's billings," then applying that rate to all billings for a five-year period. *Id.* The district court concluded that the

Government's methodology failed to account for the complexities of the case, particularly the fact that the Government conceded that at least some portion of the defendant's bills were valid. *See id.* at 1116. The court observed:

> In order to accept the picture offered by the government with respect to the entire universe of fraudulent billings, I have to accept that Skodnek almost never honestly billed a single patient, never forgot to bill for time he had actually spent with them (and thus underestimated his work), that his illegal activities never ebbed and flowed over a five or six year period.

Id. at 1117. Concluding that "[t]he trial testimony and the documentary evidence simply do not bear out these assumptions," the district court refused to admit the proffered statistical evidence. *Id.*

Similarly, in *United States v. Friedman*, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993), the District of Massachusetts declined the Government's invitation to use extrapolation to determine the defendant's liability under the FCA. In that case, the Government presented trial testimony from four experts, who had conducted a detailed medical review of a 350-claim sample, and concluded that 297 of the claims contained a materially false representation. *Id.* at *7. The Government then asked the court to extrapolate from the sample to the entire universe of 676 claims. The court refused to take this path, explaining:

> While I recognize the validity of the mathematical and statistical projections based on a review of a smaller number of claims I have declined to extrapolate in the manner urged by the government. My declination is based on the existence at trial of discrete claims which were

> analyzed and discussed and subjected to cross examination. I was able therefore to review each claim in reaching my conclusions. While I am mindful of the government's efforts to shorten the trial and present its evidence efficiently and clearly, *I am reluctant to accept a statistical sampling as the basis for doubling the alleged overpayment without the same scrutiny and support.*

Id. at *9 n.1 (emphasis added).

The Northern District of Illinois rejected statistical evidence to prove FCA liability in *United States v. Medco Physicians Unlimited*, 2000 U.S. Dist. LEXIS 5843 (N.D. Ill. Mar. 17, 2000). In *Medco*, the Government sought to extrapolate from the findings on a 16-claim sample to all claims submitted to Medicare by the defendant. *Id.* at *23. The court refused to do so, noting that there was "*no case law or other authority to support such a request*." *Id.* at *23 (emphasis added).

In addition to these cases, there are numerous others in which courts have rejected attempts to use statistical evidence to prove liability under the False Claims Act. *See, e.g.*; *United States ex rel. Crews v. NCS Healthcare*, 460 F.3d 853, 857-58 (7th Cir. 2006) (rejecting *qui tam* relator's attempt to establish FCA liability based upon percentages rather than proof of actual false claims); *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 30-31 & n.9 (D.D.C. 2008) (rejecting plaintiff's attempt to prove false certifications under the FCA through the assumption that different anesthesiologists, providing different types of anesthesia, nevertheless acted in uniform ways; requiring plaintiffs to provide the court and the defendant "with a list, *both comprehensive and exact*, of the allegedly fraudulent claims submitted to Medicare"); *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998)

(refusing to accept statistical evidence as proof of FCA liability "in light of the admittedly subjective nature of coding, the relatively small sample size, and the variation in years covered").

D. Sampling and extrapolation are most often used to quantify damages when liability is conceded or indisputable—circumstances not present in this case.

Statistical sampling is a "deviation[] from traditional modes of proof" that is only "tolerable" under rare circumstances—such as when liability is conceded and both parties consent to sampling. *Hockett*, 498 F. Supp. 2d at 67. "[W]hile case law permits the approach in general, it plainly counsels caution." *Skodnek*, 933 F. Supp. at 1115.

Attempting to give the Court the comfort of precedent, Relators cite numerous cases for in which courts—including the Fourth Circuit—allowed the use of statistical evidence to estimate the amount of damages or loss. Br. of Appellants at 12. These cases are critically different from this case, however, in that none of them involved the use of statistical sampling to prove *liability for fraud*, *i.e.*, the *knowing* submission of a false claim for payment. *See Goldstar Med. Servs., Inc. v. Dep't of Soc. Servs.*, 955 A.2d 15, 21, 31 (Conn. 2008) (approving extrapolation to determine the amount of overpayment after a "full scale audit" of 93 claims, which involved review of "department files, computerized databases and medical records," as well as site visits to nursing homes); *Ratanasen v. Cal. Dep't of Health Servs.*, 11 F.3d 1467, 1469, 1471 (9th Cir. 1993) (approving use of sampling and extrapolation to determine the amount of

overpayment following full audit of 300 claims, when the physician did not challenge the audit results); *Webb v. Shalala*, 49 F. Supp. 2d 1114 (W.D. Ark. 1999) (approving use of sampling and extrapolation after full audit of 250 claims, where there was no dispute regarding the facts of the physician's billing practices); *United States v. Conner*, 262 F. Appx. 515 (4th Cir. 2008) (holding that sampling an extrapolation was proper in determining a reasonable estimate of loss for purposes of sentencing).

Relators also point to cases approving the use of statistical sampling in Medicare recoupment cases. Br. of Appellants at 13. Recoupment, however, is a far different animal than an FCA case. Recoupment is an administrative proceeding initiated by the claims processor, in which overpayments are recovered through the reduction of future Medicare reimbursements. It is, in essence, a contractual set-off. Unlike the FCA, a recoupment proceeding is not concerned with scienter, and the burden of proof is on the payee to prove entitlement to the amounts paid. Further, recovery in a recoupment proceeding is limited to the actual amount of overpayment, plus interest. The FCA, exposes defendants to trebled damages and a fine of at least $5,000 per claim. *See* 31 U.S.C. § 3729(G). Perhaps most importantly, the use of statistical sampling and extrapolation in recoupment actions is specifically authorized by statute, provided there is evidence of "a sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3).

Relators cite a number of other cases, none of which are on point. In *United States ex rel. Harris v. Bernad*, 275 F. Supp. 2d 1 (D.D.C. 2003), the court

accepted a sampling of twelve patient files as sufficient to *avoid dismissal* under Fed. R. Civ. P. 9(b)—not to prove liability at trial. Relators discuss *United States ex rel. Barron v. Deloitte & Touche, LLP*, 2008 WL 7136869 (W.D. Tex. Sept. 26, 2008), at length, but fail to note that the case involved statistical proof of *damages*, not liability. Relators also neglect to point out that the court in that case excluded the proffered statistical evidence because it was unreliable. *See id.* at *3-4. Among other things, the court found that the plaintiffs' expert counted claims as "invalid" if certain documentation was missing, even though the absence of documentation had no bearing on the issue of whether the services provided were medically necessary. *See id.* at *3.

Relators point to *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234 (D.P.R. 2000), as an example of the use of statistical sampling to calculate damages in an FCA case. Br. of Appellants at 13-15. Given its substantial differences from this case, however, *Cabrera-Diaz* is of little help to them. Most importantly, the ruling in *Cabrera-Diaz* was entered on a motion for default judgment, and thus the defendants never attempted to challenge the government's proposed use of statistical sampling to demonstrate scienter. *See id.* at 236. Indeed, *United States ex rel. Martin v. Life Care Centers of America, Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. Sept. 29, 2014), a case heavily relied on by Relators and the Government in the district court, refused to accept *Cabrera-Diaz* as authority, concluding that "the Court cannot view the result in Cabrera–Diaz as anything other than an unopposed remedy suggested by the government, which was granted through a procedural mechanism to obtain

judgment from unresponsive parties." *Id.* at 564. To the contrary, the *Martin* court recognized that "**using extrapolation to establish damages** when liability has been proven **is different from using extrapolation to establish liability** … [which] **could be in conflict with the Government's evidentiary burden to establish the elements of a FCA claim**." *Id.* at 563 (emphasis added).

E. Statistical Sampling cannot be used to prove scienter in an FCA case.

The FCA authorizes liability only for the *knowing* submission of false claims. *See* 31 U.S.C. § 3729 (a)(1). This does not require proof of a specific intent to defraud. 31 U.S.C. § 3729(b)(1)(B). Rather, a federal contractor acts knowingly when it "has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). Phrased differently, liability under the FCA requires proof of "the knowing presentation of what is known to be false as opposed to innocence or ignorant mistake." *Mikes v. Strauss*, 274 F.3d 687, 703 (2d Cir. 2001).

Relators, bringing suit in the name of the Government, "shall be required to prove **all essential elements** of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(c) (emphasis added); 31 U.S.C. § 3730; *Harrison*, 352 F.3d at 912-13. The FCA punishes only parties who ***knowingly*** perpetrate fraud. *See United States v. DRC, Inc.*, 856 F. Supp. 2d 159, 168 (D.D.C. 2012). To prove liability under the FCA, a relator

"cannot rely on the collective knowledge of the entity's agents to establish scienter." *Fadul*, 2013 WL 781614, at *9. Rather, a relator "must prove an entity's scienter by demonstrating that a particular employee or officer acted knowingly." *Id.*

In view of this standard, it simply is not possible to prove the *knowing* submission of false claims through aggregate proof. "Welding different [statistical] inferences together cannot substitute for direct proof[.]" *Hockett*, 498 F. Supp. 2d at 66. The Relators must, for each claim, adduce evidence of falsity and scienter—and aggregate data cannot prove the falsity or scienter of an individual claim. *See, e.g., Visiting Nurse Ass'n*, 378 F. Supp. 2d at 99 ("This court concludes that the government is not entitled to collect penalty damages for each of the thousands of interim reimbursement claims submitted by the Providers because there has been no allegation that any aspects of the reimbursement claims themselves were false or fraudulent."); *Quinn*, 382 F.3d at 438 (determining that defendant did not "intentionally mak[e] any misrepresentation"). Thus, this Court should reject Relators' proposal to introduce statistical sampling to prove their FCA allegations.

CONCLUSION

"While innovation is to be encouraged, the rights of the parties may not be sacrificed for the sake of expediency." *Duran v. U.S. Bank Nat'l Ass'n*, 137 Cal. Rptr. 3d 391, 420 (Cal. Ct. App. 2012), *aff'd*, 325 P.3d 916 (Cal. 2014). That is exactly what Relators seek to do here, through the use of statistical sampling and extrapolation as a substitute for direct proof. It was Relators' choice to sue all 26 Agape entities when they had only worked in one. Having pleaded such a large case, Relators sought to use statistical sampling to avoid their burden, as the plaintiffs, of proving that Agape knowingly submitted claims to Medicare for hospice services based on false (not merely erroneous) hospice-eligibility certifications. But "convenience alone cannot justify procedures that substantially curtail the parties' ability to litigate their case." *Duran*, 325 P.3d at 42. The district court properly concluded that statistical sampling was not an appropriate means of proof in this case, and its ruling should be affirmed.

Signature page follows.

Respectfully submitted,

s/ William W. Wilkins
William W. Wilkins
Kirsten E. Small
Mark C. Moore
William. C. Lewis
Nexsen Pruet, LLC
Post Office Drawer 10648
Greenville, SC 29603
(864) 370-2211
BWilkins@nexsenpruet.com
KSmall@nexsenpruet.com

Deborah B. Barbier
Deborah B. Barbier Attorney at Law
1531 Laurel Street
Columbia, SC 29201
PHONE: 803.445.1032
FACSIMILE: 803.445.1036
dbb@deborahbarbier.com

Attorneys for Defendants-Appellees

March 17, 2016
Greenville, South Carolina